products liability claims by breast implant recipients. Pet. App. 157-158a, 160a-161a (Compl. ¶¶ 43-44, 58-59, 67-68). Second, the complaint alleges that petitioners alternatively or additionally were responsible for reimbursing the Medicare program as entities that "received payment" (42 U.S.C. 1395y(b)(2)(B)(ii)) from their products liability insurers with respect to implant-related claims. Pet. App. 158a, 161a (Compl. ¶¶ 45-46, 64-65).

b. The district court dismissed the complaint for failure to state a claim. Pet. App. 71a-108a. Although the court offered various grounds for its ruling, only two are relevant to the petition.

First, in dismissing the "self-insurance" counts, the court declared that the statutory term "self-insured plan" does not encompass entities that self-insure only in part, by purchasing excess insurance that is triggered after a liability threshold is met. Pet. App. 84a & n.12. The court opined, further, that a "self-insured plan" necessarily requires "some type of formal arrangement by which funds are set aside and accessed to cover future liabilities," *id.* at 84a, factors that the government had not specifically alleged in its complaint.

Second, the court concluded that petitioners could not be held liable as entities that "received payment" from another insurance plan responsible for reimbursing Medicare, notwithstanding petitioners' alleged receipt of the proceeds of their products liability insurance. In the court's view, petitioners must be regarded as mere "pass-through" entities between their own insurers and the implant recipients. Pet. App. 95a-100a.

c. A unanimous panel of the Eleventh Circuit reversed in relevant part, remanding the case for dis-

covery and other further proceedings. Pet. App. 1a-70a.

Addressing the district court's "self-insurance" rulings, the court rejected the conclusion that the statutory term "self-insured" could not apply to entities that self-insure only in part, by carrying their own risk up to a certain amount and procuring insurance policies to cover the excess. Pet. App. 42a-47a. The court observed that, to prevent responsible parties from eluding MSP liability, the Secretary's regulations defined the statutory term "self-insured" broadly as a plan under which an entity "carries its own risk instead of taking out insurance with a carrier." *Id.* at 45a (quoting 42 C.F.R. 411.50(b)). The court explained that there was "nothing in the plain meaning of the statute which might preclude the agency's interpretation to include within the self-insured concept the commonly occurring circumstances of an individual or entity planning ahead of time to assume responsibility and liability for certain risks up to a designated amount, and to procure an insurance policy to cover the excess." *Id.* at 47a. To the contrary, the court reasoned, while some authorities interpret the term "self-insured plan" rigidly, it "is interpreted by other authorities to include precisely such a combination of self-insurance up to a certain amount with the excess to be covered by an insurance policy." *Ibid.*; see, *e.g.*, *id.* at 48a n.23 (noting that the 1979 edition of *Black's Law Dictionary* (at 1220) explained, in defining self-insurance, that "[a] common practice of businesses is to self-insure up to a certain amount, and then to cover any excess with insurance").

The court of appeals similarly rejected the district court's conclusion that the term "self-insured plan" requires proof of a formal arrangement by which funds were set aside and providers were made to use them to

cover future liabilities. Pet. App. 42a-52a. The court noted that the agency's regulations define the term "plan" to include "any arrangement, oral or written, by one or more entities, to . . . assume legal liability for injury or illness," *id.* at 45a (quoting 42 C.F.R. 411.21), and that the inclusion of the term "oral" suggested "an intent to reach informal, ad hoc arrangements in addition to traditional insurance policies." *Ibid.* The court held that the agency's view was "especially persuasive in the absence of a universally accepted and authoritative definition of 'self-insured plan' which Congress might have contemplated in drafting the statute." *Ibid.*; see, *e.g.*, *id.* at 47a ("Even the sparse legal authority which suggests that there usually will be a reserve for losses, also indicates that 'self-insurance' has no precise legal meaning."). Although the court disagreed with *dicta* in the Fifth Circuit's decision in *Thompson* v. *Goetzmann*, 315 F.3d 457 (2002), opinion withdrawn and reissued as amended on other grounds, 337 F.3d 489 (5th Cir. 2003), suggesting that a formal set-aside of funds was required, the court "fully agree[d] with the Fifth Circuit that the term 'plan' in the statutory term 'self-insured plan' clearly contemplates an *ex ante* arrangement." Pet. App. 49a.

In its "received payment" ruling, the court of appeals remanded to allow the government an opportunity to prove that petitioners may be held liable, based on their alleged receipt of the proceeds of their products liability insurance policies, under the statutory provision allowing the government to recover from "any other entity (including any physician or provider) that has received payment" from any primary plan. Pet. App. 64a (quoting 42 U.S.C. 1395y(b)(2)(B)(ii)). The court explained that it could assume that "Congress intended the term 'any other entity' to be understood with reference to

'physician' and 'provider,' and to encompass only entities of like kind." *Id.* at 65a. The court further observed that, although the record is "devoid of detail about the role of [petitioners'] liability insurance carriers," it appears that petitioners "initially financed the settlement, then filed claims with their insurers, which will provide reimbursement based on their independent evaluation of the class members' claims." *Id.* at 68a. The court explained that, if so, the district court's description of petitioners as "mere intermediaries between their insurance companies and the class members is not accurate." *Ibid.* The court remanded to allow the government to develop evidence relevant to this aspect of the suit. *Id.* at 68a-69a.

d. The court of appeals denied the petitions for rehearing and rehearing en banc, no active judge having asked for a vote on the en banc petition. Pet. App. 111a-112a.

3. On December 8, 2003, after the panel issued its decision in this case, the President signed into law the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066. Section 301 of that Act amends the MSP provisions in a manner that largely codifies the interpretations of the Secretary of Health and Human Services on the issues raised by the petition. The title of Section 301(b) reflects that Congress regarded these amendments as "[c]larifying" the MSP statute. 117 Stat. 2221. Section 301(d) further provides that the amendments in Section 301(b) are effective as if included in the MSP statute as originally enacted in 1980. 117 Stat. 2222.

As particularly relevant here, Section 301(b)(1) provides that "[a]n entity that engages in a business, trade, or profession shall be deemed to have a self-

insured plan if it carries its own risk (*whether by failure to obtain insurance, or otherwise*) *in whole or in part.* 117 Stat. 2222 (emphases added). That provision accordingly makes clear that the existence of a self-insured plan does not depend upon a formal set aside of funds or formal claims procedures, and that an entity that has procured liability insurance may nonetheless be considered to be self-insured for any amount for which the entity carries its own risk.

Additionally, Section 301(b)(3) of the 2003 Act also deletes the parenthetical phrase "including any physician or provider" from the "received payment" provision of the MSP statute, and provides that "the United States may recover under this clause from any entity that has received payment from a primary plan or from the proceeds of a primary plan's payment to any entity." 117 Stat. 2222; accord *ibid.* (Section 301(b)(2) amends the MSP statute to provide that "[a] primary plan, and an entity that receives payment from a primary plan, shall reimburse" the Medicare program for the payments it has made). Those amendments leave no doubt that the Secretary has a cause of action to seek reimbursement from entities such as petitioners that are alleged to have received payment from a primary plan, including a traditional liability insurance plan.

ARGUMENT

The interlocutory decision of the court of appeals interpreting the prior version of the MSP statute is correct and does not squarely conflict with the decision of this Court or of another court of appeals. To the extent that there is tension between the decision below and *dicta* from other courts of appeals concerning that prior version, the issues have been resolved by the

December 2003 amendments to the Medicare Secondary Payer statute. Accordingly, the petition for writ of certiorari should be denied.

1. Petitioners do not dispute that the 2003 amendments confirm the positions of the Secretary on the questions raised by the petition and that those amendments—not the provisions in effect when the court of appeals decided the case—will now govern the further proceedings in this case. Moreover, petitioners expressly do not present a constitutional challenge to the 2003 amendments (see Pet. 29). The petition nonetheless seeks review of the court of appeals' interpretation of prior law because petitioners assert that the law of the case doctrine will bar them from later raising a constitutional challenge to the amendments. Pet. 29-30. The court of appeals' decision, however, is purely interlocutory, and nothing would prevent petitioners from raising in this Court any issue—including a constitutional challenge and any issue concerning the prior law that might be relevant to such a challenge—after the entry of final judgment. There is, moreover, no reason at the present time to conclude that the questions petitioners seek to raise now will warrant the Court's review even after entry of a final judgment —assuming that petitioners are found liable in proceedings on remand, that they raise a constitutional challenge to their liability under the 2003 amendments in these proceedings, and that an interpretation of propr law appears relevant to their challenge at that time. Congress has expressed its view that the 2003 amendments clarify, rather than change, the MSP statute. Pub. L. No. 108-173, § 301(b), 117 Stat. 2221 (title describes the provisions in Section 301(b) as "Clarifying Amendments To Conditional Payment Provisions"). Such a congressional declaration about the

meaning of an earlier statute is itself given great weight. *Loving* v. *United States*, 517 U.S. 748, 770 (1996) ("[s]ubsequent legislation declaring the intent of an earlier statute is entitled to great weight") (quoting *Consumer Prod. Safety Comm'n* v. *GTE Sylvania, Inc.*, 447 U.S. 102, 118 n.13 (1969), and *Red Lion Broad. Co.* v. *FCC*, 395 U.S. 367, 380-381 (1969)). Moreover, if the Court concluded that review were warranted at that time, it would have the benefit of a more fully developed factual record, and would be able to consider the constitutional challenge in that context.

In any event, petitioners are manifestly incorrect in arguing (Pet. 26) that the 2003 amendments have "unsettled the expectations" of parties who either receive or make a payment relating to medical expenses for which the Secretary has previously made payment under Medicare. Petitioners do not (and cannot) dispute that the payment of products liability insurance proceeds on the basis of implant-related claims is precisely the sort of insurance coverage that triggers the MSP statute's obligation to reimburse Medicare. To the contrary, petitioners' contention in this litigation has largely been that the government may proceed only against the implant recipients. Cf. Pet. App. 52a n.28 (declining to address the argument that the government must attempt to recover from the class members before it may seek reimbursement from the manufacturers).

Petitioners' contention that the 2003 amendments unconstitutionally upset their own settled expectations is also incorrect. The government put petitioners on notice in 1994 (before they entered into the RSP) that, to the extent the government had made Medicare payments for the victims' implant-related medical care, reimbursement was required under the MSP statute.

Petitioners nonetheless thereafter chose at their own risk to make or direct settlement payments to implant recipients without regard to whether Medicare had paid for their medical care.

2. Petitioners argue (Pet. 17-22) that they cannot be regarded as maintaining self-insured plans because they are alleged to have conventional liability insurance for amounts in excess of those for which they carry their own risk. The court of appeals correctly rejected petitioners' contention that they cannot be regarded as having "self-insured" plans within the meaning of the MSP statute unless they carry their *entire* risk. As the court of appeals explained, ample authority supports the agency's interpretation that an entity may combine "self-insurance up to a certain amount with the excess to be covered by an insurance policy." Pet. App. 47a; see also *Black's Law Dictionary* 1220 (5th ed. 1979) ("A common practice of businesses is to self-insure up to a certain amount, and then to cover any excess with insurance.").

Contrary to petitioners' assertion (Pet. 15), the court of appeals' decision does not conflict with the Second Circuit's decision in *Mason* v. *American Tobacco Co.*, 346 F.3d 36 (2003), cert. denied, No. 03-1270 (May 17, 2004), or the Fifth Circuit's amended decision in *Thompson* v. *Goetzmann*, 337 F.3d 489 (2003). As the court of appeals observed, there was no suggestion in *Mason* that the tortfeasor had purchased any insurance. Pet. App. 46a n.22. Nor was there any such indication in *Goetzmann*, as petitioners acknowledge. See Pet. 17 ("The record in *Goetzmann* demonstrated that Zimmer had elected not to purchase product liability insurance[.]").

In any event, the December 2003 amendments to the MSP statute leave no doubt that a business entity shall

be deemed to have a "self-insured plan" if it carries its own risk "in whole or *in part*." Pub. L. No. 108-173, § 301(b)(1), 117 Stat. 2222 (emphasis added). Congress has thus resolved the issue that petitioners ask this Court to decide.

3. Petitioners also argue (Pet. 17-22) that they cannot be understood to have a "self-insured plan" within the meaning of the MSP statute unless they have formal procedures by which funds are set aside and then subject to claims to cover future liabilities. As the court of appeals explained, however, the Secretary has interpreted the statutory term "self-insured plan" broadly to include oral and other informal arrangements to assume liability. Pet. App. 45a; 42 C.F.R. 411.21. To be sure, under the Secretary's regulation interpreting the prior version of the MSP statute, "the mere absence of insurance purchased from a carrier does not necessarily constitute a 'plan' of self-insurance." 54 Fed. Reg. 41,727 (1989). As the court of appeals observed, both the statute and the regulation contemplate some form of "*ex ante* arrangement," and a tortfeasor's discrete settlement payment in a particular case does not by itself establish that it has a self-insured plan. Pet. App. 49a. As the court of appeals further explained, however, neither the statute nor the regulation imposes the additional requirement of a set-aside of funds or other formal procedures. *Id.* at 47a-48a; cf. 29 U.S.C. 1081(a)(1) (exempting welfare benefit plans from ERISA's funding requirements).

Although there are *dicta* in *Goetzmann* suggesting that a formal set-aside of funds is required, any tension between that decision and the decision below does not warrant this Court's review, particularly in light of the December 2003 amendments. As amended, the MSP statute provides that "[a]n entity that engages in a

business, trade, or profession shall be deemed to have a self-insured plan if it carries its own risk (*whether by failure to obtain insurance, or otherwise*) in whole or in part. Pub. L. No. 108-173, § 301(b)(1), 117 Stat. 2222 (emphasis added). The amendment thus makes clear that no set-aside of funds or formal mechanism for payment of claims is required.

Moreover, the holding of *Goetzmann* is narrow. As the court of appeals in this case explained (Pet. App. 49a & n.24), the Fifth Circuit perceived the government's complaint in *Goetzmann* to allege that the tortfeasor was self-insured merely by virtue of its payment in settlement of a single tort claim. See, *e.g.*, *Goetzmann*, 337 F.3d at 495 ("In this case, the 'self-insurance plan' is alleged by the government to exist by virtue of Zimmer's payment to Medicare recipient Loftin under the terms of their products-liability settlement agreement."). *Goetzmann* thus stands for the unremarkable proposition that "an alleged tortfeasor who settles with a plaintiff is not, *ipso facto*, a 'self-insurer' under the MSP statute." *Id.* at 497.[2] The court of appeals in this case "fully agree[d]" with that aspect of the Fifth Circuit's decision. Pet. App. 49a.

In *Mason*, the Second Circuit expressly distinguished the court of appeals' decision in this case. 346 F.3d at 41-42. *Mason* was a private suit under the MSP statute; the government was not a party. The Second Circuit stressed that the private plaintiffs in *Mason* had

---

[2] The government's rehearing petition in *Goetzmann* explained that the panel had misunderstood the government's argument. Pet. for Reh'g En Banc at 14-15, *Thompson* v. *Goetzmann*, 337 F.3d 489 (5th Cir. 2003) (No. 02-10198); Pet. for Panel Reh'g at 1, 12-13, *Goetzmann*, *supra* (No. 02-10198). The panel nonetheless chose to reissue the self-insurance portion of its decision unchanged.

not even established that the defendants were responsible to pay for anyone's medical care. *Id.* at 42. The court explained that, by contrast, the RSP settlement in this case left no doubt about the breast implant manufacturers' responsibility to pay. *Ibid.*

4. Petitioners also argue that they cannot be held liable based on their alleged receipt of payments under product liability insurance plans because they are simply pass-through entities who received payment under a primary plan. Pet. 22-25. The court of appeals assumed, however, that mere "pass-through" payers would not be covered by the MSP statute. Pet. App. 65a. Indeed, the court of appeals affirmed the district court's judgment insofar as it dismissed the damages count against the escrow agent who administers settlement funds, observing that the "uncontested evidence is that the Escrow Agent acts in a purely ministerial role serving the district court." *Ibid.*

By contrast, however, the court observed that the district court's characterization of petitioners as "mere intermediaries" might well prove inaccurate, with the benefit of discovery. Pet. App. 68a. That interlocutory ruling does not warrant this Court's review. Although petitioners allege a conflict with the D.C. Circuit's *HIAA* decision, *HIAA* merely held that a third-party administrator of an employer group health plan could not be held liable based on its receipt of payment from the plan. 23 F.3d at 415-417. The *HIAA* decision has no bearing on the government's claims against petitioners, whose right to the proceeds of their insurance policies cannot plausibly be equated with a third-party administrator's temporary possession of funds intended to pay liabilities for which the administrator has no personal liability. Petitioners would have received any of the funds at issue in their capacities as *insureds*

under policies that were intended to cover the very sort of injuries that led to Medicare payments, and would have received them precisely because of their responsibility for the injuries to the victims. Petitioners are not mere intermediaries, or like a bank that is clearing a check.

Moreover, the December 2003 amendments delete the parenthetical phrase "including any physician or provider," and thus make clear that there is no basis for narrowly interpreting the category of entities liable to reimburse Medicare when they receive payment from their liability insurance carriers. Pub. L. No. 108-173, § 301(b)(3), 117 Stat. 2222 (the federal government may recover "from any entity that has received payment from a primary plan or from the proceeds of a primary plan's payment to any entity"); Pub. L. No. 108-173, § 301(b)(2), 117 Stat. 2222 ("[a] primary plan, and an entity that receives payment from a primary plan, shall reimburse" the Medicare program for the payments it has made). The government is accordingly entitled to the proceeds allegedly received by petitioners under any primary plan which unquestionably includes a product liability insurance plan. 42 U.S.C. 1395y(b)(2).

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

THEODORE B. OLSON
Solicitor General

PETER D. KEISLER
Assistant Attorney General

MARK B. STERN
ALISA B. KLEIN
Attorneys

MAY 2004

Supreme Court, U.S.
FILED
JUN 3 - 2004
OFFICE OF THE CLERK

No. 03-1341

In the Supreme Court of the United States

BAXTER INTERNATIONAL INC., BAXTER HEALTHCARE CORPORATION, BRISTOL-MYERS SQUIBB COMPANY, MINNESOTA MINING AND MANUFACTURING COMPANY AND UNION CARBIDE CORPORATION,

PETITIONERS,

v.

UNITED STATES OF AMERICA,

RESPONDENT.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

PETITIONERS' REPLY BRIEF

PETER W. MORGAN
MARIA COLSEY HEARD
DICKSTEIN SHAPIRO MORIN & OSHINSKY LLP
2101 L STREET, NW
WASHINGTON, DC 20037
(202) 785-9700

Counsel for Baxter International Inc. and Baxter Healthcare Corporation

Additional Counsel Listed on Inside Cover

MAUREEN E. MAHONEY
Counsel of Record
MILES N. RUTHBERG
LATHAM & WATKINS LLP
555 11TH STREET, NW
SUITE 1000
WASHINGTON, DC 20004
(202) 637-2200

Counsel for Minnesota Mining and Manufacturing Company

WILLIAM A. KROHLEY
KELLEY DRYE & WARREN LLP
101 PARK AVENUE
32ND FLOOR
NEW YORK, NY 10178
(212) 808-7800

Counsel for Union Carbide Corporation

RICHARD M. EITTREIM
JERRY P. SATTIN
MCCARTER & ENGLISH, LLP
FOUR GATEWAY CENTER
100 MULBERRY STREET
NEWARK, NJ 07102
(973) 622-4444

Counsel for Bristol-Myers Squibb Company

TABLE OF CONTENTS

Page

TABLE OF CONTENTS i
TABLE OF AUTHORITIES ii
ARGUMENT 1
CONCLUSION 10

TABLE OF AUTHORITIES

Page(s)

CASES

Cipollone v. Liggett Group, Inc.,
505 U.S. 504 (1992) 8

Consumer Product Safety Commission v. GTE Sylvania, Inc.,
447 U.S. 102 (1980) 8

Department of Commerce v. United States House of Representatives,
525 U.S. 316 (1999) 7

Gillespie v. United States Steel Corp.,
379 U.S. 148 (1964) 9, 10

Health Insurance Association of America, Inc. v. Shalala,
23 F.3d 412 (D.C. Cir. 1994), *cert. denied*, 513 U.S. 1147 (1995) 3

Loving v. United States,
517 U.S. 748 (1996) 8

Mackey v. Lanier Collection Agency & Service, Inc.,
486 U.S. 825 (1988) 8

Mason v. United Tobacco Co.,
346 F.3d 36 (2d Cir. 2003), *cert. denied*, 72 U.S.L.W. 3712 (U.S. May 17, 2004) 2, 8

O'Gilvie v. United States,
519 U.S. 79 (1996) 8

TABLE OF AUTHORITIES—Continued

Page(s)

Red Lion Broadcasting Co. v. FCC,
395 U.S. 367 (1969) 8

Thompson v. Goetzmann,
337 F.3d 489 (5th Cir. 2003) 1, 2, 8

United States v. Baxter International, Inc.,
345 F.3d 866 (11th Cir. 2003) 8

United States v. General Motors Corp.,
323 U.S. 373 (1945) 9, 10

United States v. Philip Morris Inc.,
156 F. Supp. 2d 1 (D.D.C. 2001) 2

Waters v. Farmers Texas County Mutual Insurance Co.,
9 F.3d 397 (5th Cir. 1993) 6

STATUTES AND REGULATIONS

42 U.S.C. § 1395x(v) 5
42 U.S.C. § 1395y(b)(2)(B)(iii) 3

Pub. L. No. 108-173, § 301(b)(1), 117 Stat. 2066, 2222 (2003) 8

42 C.F.R. § 411.24(g) 6
42 C.F.R. § 413.100(b)(2) 5
42 C.F.R. § 413.100(c)(2)(viii) 5

OTHER AUTHORITY

54 Fed. Reg. 41,716 (Oct. 11, 1989) 8

TABLE OF AUTHORITIES—Continued

Page(s)

1 Eric Mills Holmes & Mark S. Rhodes, *Holmes's Appleman on Insurance* § 2.16 (2d ed. 1996) 4

CMS Pub. 15-1 (http://www.cms.hhs.gov/manuals/pub151/PUB_15_1.asp)..... 5

ARGUMENT

1. The Government's attempt to characterize the decision below as creating mere "tension" with "dicta" from other circuits fails. Petitioners would have prevailed under the legal standards adopted in other circuits.

The Fifth Circuit. As explained in detail in the petition at 17-19, *Thompson v. Goetzmann*, 337 F.3d 489 (5th Cir. 2003), dismissed the Government's MSP complaint against a product manufacturer that settled a claim with a Medicare beneficiary for failure to allege facts sufficient to satisfy the definition of a "primary plan" under the MSP. *See also* Opp. at 15. The Court explained in unequivocal terms that "in the sense used in the MSP statute, a 'primary plan' of 'self-insurance' requires an entity's *ex ante* adoption, for itself, of an arrangement for (1) a source of funds and (2) procedures for disbursing these funds when claims are made against the entity." 337 F.3d at 498. The Government's complaint in this case similarly fails to allege any facts that would satisfy this definition of a "primary plan." Indeed, the Fifth Circuit cited the district court decision dismissing the Government's complaint *in this case* with approval. *Id.* at 499 n.26.

Instead of conceding this obvious conflict, the Government first asserts that *Goetzmann* is inapposite because the settling manufacturer had not purchased any product liability insurance whereas Petitioners did. Opp. at 16. The Government fails to explain why this factual distinction could possibly matter. If a manufacturer that purchases *no* coverage is not "self-insured" under the Fifth Circuit's interpretation of the MSP then surely a manufacturer that purchases insurance is not "self-insured."

The Government next contends there is no conflict because the Fifth Circuit merely held that "'an alleged tortfeasor who settles with a plaintiff is not, *ipso facto*, a "self insurer."'" Opp. at 15 (quoting 337 F.3d at 497). That circumscribed reading of the opinion is unpersuasive. The Fifth Circuit clearly held that any attempt to amend the allegations of self-insurance would be futile. *See* Pet. at 18

n.15. It explained that "[t]he term 'primary plan' is pivotal to the applicability of the MSP statute" (337 F.3d at 497); the definition of that term, when applied to self-insured plans, requires the advance creation of a fund to cover anticipated liabilities and procedures for disbursement (*id.* at 498); and the Government never contended in *Goetzmann* (or here) that it could allege those "pivotal" facts.

The Second Circuit. The Second Circuit also upheld the dismissal of an MSP complaint against product manufacturers for failure to allege facts sufficient to establish that they maintained self-insured plans within the meaning of the MSP. Like the Fifth Circuit in *Goetzmann*, the Second Circuit expressly adopted a definition of self-insured plan that requires that the settling tortfeasor acted as an insurance carrier for itself by creating a fund and disbursement procedures for future liabilities. *Mason v. United Tobacco Co.*, 346 F.3d 36, 41 (2d Cir. 2003), *cert. denied*, 72 U.S.L.W. 3712 (U.S. May 17, 2004).

The Government contends that *Mason* can somehow be reconciled with the decision below because "there was no suggestion in *Mason* that the tortfeasor had purchased any insurance." Opp. at 13. The Court's reasoning, however, reveals that it would be even less likely to find that tortfeasors that purchase insurance are self-insured. The Court emphasized that the "'logical implication'" of a definition of a self-insured plan that did not require a set aside of funds was that any entity "'with a risk of legal liability which chooses to retain any portion of that risk, no matter how small, may be pursued under MSP on the ground that it is a "self-insured plan."'" *Mason*, 346 F.3d at 40 (quoting *United States v. Philip Morris Inc.*, 156 F. Supp. 2d 1, 7 (D.D.C. 2001)). Nor can *Mason* be distinguished on the theory that "the RSP settlement in this case left no doubt about the breast implant manufacturers' responsibility to pay." Opp. at 16. The Court's observation that the RSP Defendants had "assumed obligations to pay" was based upon a misunderstanding of the record here. As

the Second Circuit understood, the MSP predicates liability on a showing that the defendant is "required or responsible . . . to make payment . . . *under a primary plan.*" 42 U.S.C. § 1395y(b)(2)(B)(iii) (emphasis added). What the Second Circuit obviously did not know is that the Government disavowed any claim that the RSP was a "primary plan" (Pet. at 19-20 n.16). Thus, the fact that Petitioners assumed a "responsibility to pay" under "the RSP settlement" (Opp. at 16), is of no legal consequence because the RSP is not a "primary plan."

The D.C. Circuit. The Eleventh Circuit's analysis of Petitioners' potential liability as entities that "received payment" cannot be reconciled with *HIAA*, where the D.C. Circuit squarely held that Congress required the Government to sue the *insurer* and not a pass-through payer, except in limited circumstances. *Health Ins. Ass'n of Am., Inc. v. Shalala*, 23 F.3d 412, 416-17 (D.C. Cir. 1994) ("*HIAA*"), *cert. denied*, 513 U.S. 1147 (1995). As explained in the Petition at 24, the Eleventh Circuit reasoned that *HIAA* was distinguishable based upon the mistaken premise that the third-party administrator would have no involvement in any decision to make a payment to a claimant. The Government makes no effort to defend this reasoning. It instead asserts that *HIAA* has "no bearing" on the issue here because Petitioners, unlike the third-party administrator in *HIAA*, have "personal liability" to the claimants under the RSP. Opp. at 16. The operative legal issue in *HIAA*, however, is whether the party handling the primary payment "assume[d] financial responsibility for paying a plan's benefits." 23 F.3d at 416. Nothing in the Government's complaint does or could allege that Petitioners assumed financial responsibility for making liability insurance payments. The D.C. Circuit's analysis accordingly leaves no doubt that it would not permit the Government to bypass the insurer and "proceed directly against [settling tortfeasors]." *Id.* at 417.